

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*County of Summit, et al. v. Purdue
Pharma L.P., et al*; Case No. 1:18-

op-45090

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**PLAINTIFFS' OPPOSITION TO
MALLINCKRODT PLC's MOTION TO
DISMISS FOR LACK OF PERSONAL
JURISDICTION**

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INTRODUCTION

Mallinckrodt plc calls itself “the largest U.S. supplier of opioid pain medications.”¹ Between 1996 and 2017, Mallinckrodt plc (and its predecessor entity) reported gross sales of opioid products in the amount of [REDACTED].² Mallinckrodt also claimed approximately [REDACTED] market share of opioids medications nationally.³ In Ohio, Mallinckrodt subsidiaries dominated and controlled by Mallinckrodt, plc, were listed as the “labeler”⁴ on [REDACTED] by dosage of opioids from 2006 through 2014, which amounted to more than [REDACTED] opioid doses.⁵ Between 1997 and 2017, one Ohio-based drug distributor, Cardinal Health, purchased roughly [REDACTED] worth of Mallinckrodt’s opioids-related products.⁶ During that same time period, four other Ohio companies purchased more than [REDACTED] of Mallinckrodt’s opioid-related products. *Id.*

Mallinckrodt was founded in St. Louis, Missouri in 1867.⁷ Over the years, it was acquired and spun off several times. In 2013, after being spun off from a prior corporate entity, Covidien, Mallinckrodt executed a corporate “inversion,” whereby it incorporated Mallinckrodt plc as a public company in Ireland, evidently to enjoy favorable corporate tax treatment.⁸ This corporate

¹ Declaration of Alec Fahey, CPA (“Fahey Dec.”) at 4, 13, Fahey Exs. 9, 26 at 3.

² Ninety percent of all sales of Mallinckrodt products are in the U.S. Fahey Dec. at 7.

³ Summit’s Third Am. Compl. (“TAC”) at ¶ 96.

⁴ “Labeler” is defined as “any firm that manufactures or distributes a drug product.” See Ex. 1 to the Declaration of Mark Chalos (“Chalos Dec.”) at 8. (*ARCOS Registrant Handbook-Section 5.0 - Transaction Record*, U.S. D.O.J., <https://www.deadiversion.usdoj.gov/arcos/handbook/section5.htm#1>)

⁵ The ARCOS data [REDACTED] See Chalos Ex. 2, Summaries of ARCOS data.

⁶ See Chalos Ex. 3.

⁷ Fahey Dec. at 4, see also TAC at ¶ 94.

⁸ Mallinckrodt evidently does not dispute that its claim of an Ireland address is for tax purposes. As Mallinckrodt CEO Mark Trudeau stated, Mallinckrodt would not return its tax address to the United States unless there were a “pretty dramatic change to the US tax code.” (*Mallinckrodt Won’t Give Up Irish Home*, The Irish Times (Dec. 8, 2015 2:35 p.m.), <https://www.irishtimes.com/business/health-pharma/mallinckrodt-won-t-give-up-irish-home-1.2458692>; see also Nathan Vardi, *How Hedge Funds are Pushing Companies to Leave America*, Forbes (May 1, 2014 12:00 p.m.), <https://www.forbes.com/sites/nathanvardi/2014/05/01/how-hedge-funds-are-pushing-companies-to-leave-america/#38640109a9af>) (“Prominent hedge funds are helping to fuel the wave of so-called inversion deals that are structured to lower tax rates by moving the domiciles of U.S. companies, particularly those operating in the pharmaceuticals sector, to foreign jurisdictions like Ireland.”).

inversion is the basis of Mallinckrodt's argument in its Motion to Dismiss for Lack of Personal Jurisdiction (Dkt. No. 1266). But its purported presence in Ireland is a sham, at least for analyzing personal jurisdiction.

Mallinckrodt plc serves as the parent company of the business units, Mallinckrodt LLC and SpecGx LLC, which have sold [REDACTED] in opioids in Ohio and elsewhere in the U.S. Mallinckrodt plc dominates the operations of these subsidiaries such that the companies "do not exist as separate entities but are one and the same for purposes of jurisdiction." *Anwar v. Dow Chem. Co.*, 876 F.3d 841, 848 (6th Cir. 2017). In short, Mallinckrodt LLC and SpecGx LLC operated as agents and alter egos of Mallinckrodt plc such that they should be considered a single entity for purposes of determining personal jurisdiction. As detailed below, the companies:

- (1) share the same employees and corporate officers;
- (2) engage in the same business enterprise;
- (3) use the same assets;⁹
- (4) do not maintaining separate books and financial statements; and
- (5) Mallinckrodt plc exerts control over the daily business affairs of Mallinckrodt LLC and SpecGx LLC.

It was perhaps put best by a member of Mallinckrodt's senior leadership, Hugh O'Neill, who, after listing members of Mallinckrodt plc's board of directors during a deposition answer, did not know which company the board of directors were nominally associated with:

⁹ Mallinckrodt plc considers all of the units to be unified; For example, plc refers to them collectively as "we" in its government filings: "In addition, *we* have other locations in the United States ("U.S."), most notably *our* corporate shared services office in Hazelwood, Missouri, *our* Specialty Brands commercial headquarters in Bedminster, New Jersey and *our* Specialty Generics headquarters and technical development center in Webster Groves, Missouri. Chalos Ex. 4, 2017 MNK 10-K at 5 (emphasis added).



Chalos Ex. 5, O'Neill Dep. Tr. at 17:22-18:7.

Accordingly, the Court should similarly think about is as “it’s Mallinckrodt” and should reject Mallinckrodt plc’s threshold attempt to avoid accountability for the damages caused by billions of dollars’ worth of Mallinckrodt’s opioids sold in Ohio.

SUMMARY OF ARGUMENT

Significantly, no Mallinckrodt defendant has disputed that Mallinckrodt LLC and SpecGx LLC are subject to jurisdiction in Ohio and that such jurisdiction comports with due process. Mallinckrodt plc’s motion turns entirely on its contention that it is distinct from Mallinckrodt LLC and SpecGx LLC. The acts that Mallinckrodt LLC and SpecGx LLC engaged in – the marketing and sale of opioids into Ohio– are properly attributable to Mallinckrodt plc; it then follows that jurisdiction over Mallinckrodt plc is reasonable as well. Similarly, Mallinckrodt plc does not dispute that its predecessor Covidien sold opioids in Ohio; because Mallinckrodt plc is the successor to Covidien, again, jurisdiction is proper. Finally, Mallinckrodt plc was complicit in criminal activity of Mallinckrodt LLC and/or SpecGx LLC and other defendants, so jurisdiction is proper on that basis, too. Plaintiffs have more than established a *prima facie* case that these contentions are well supported by the facts.

LEGAL STANDARD

Where the Court rules on a motion to dismiss for lack of personal jurisdiction based on written submissions, without holding an evidentiary hearing, plaintiffs’ burden is slight: a plaintiff need only make a *prima facie* showing that jurisdiction exists in order to avoid

dismissal.¹⁰ *Anwar*, 876 F.3d at 847; accord *MAG IAS Holdings, Inc. v. Schmückle*, 854 F.3d 894, 899 (6th Cir. 2017); *Carrier Corp. v. Outokumpu Oyj*, 673 F.3d 430 (6th Cir. 2012); *Kerry Steel, Inc. v. Paragon Indus., Inc.*, 106 F.3d 147, 149 (6th Cir. 1997). “Dismissal in this procedural posture is proper only if all the specific facts which the plaintiff alleges collectively fail to state a *prima facie* case for jurisdiction.” *Kerry Steel*, 106 F.3d at 149. In assessing a plaintiff’s *prima facie* case, the court must “consider pleadings and affidavits in a light most favorable to the plaintiff, without weighing the controverting assertions of the party seeking dismissal.” *Anwar*, 876 F.3d at 847; accord *Theunissen v. Matthews*, 935 F.2d 1454, 1459 (6th Cir. 1991).¹¹

Moreover, “where the disputed jurisdictional facts are intimately intertwined with the parties’ dispute on the merits, a trial court should not require plaintiffs to mount proof which would, in effect, establish the validity of their claims and their right to the relief sought.” *Serras v. First Tennessee Bank Nat. Ass’n*, 875 F.2d 1212, 1215 (6th Cir. 1989). Instead, the court should defer determination of the jurisdictional issue for trial. Postponing proof until trial in this situation not only conserves judicial resources by permitting the court to hold “but one hearing on the contested facts,” it also “allows a plaintiff to present all her proof in a coherent, orderly fashion and without the risk of prejudicing his case on the merits.” *Id.*

¹⁰ A Kentucky state court recently denied without prejudice a similar motion to dismiss for lack of personal jurisdiction by Mallinckrodt plc and permitted plaintiff to take jurisdictional discovery, which is ongoing. Chalos Ex. 6, Order Denying Mot. to Dismiss at 2, *Commonwealth of Kentucky ex. rel. Andy Beshear v. Mallinckrodt plc, Mallinckrodt LLC, SpecGx LLC*, C.A. No. 18-CI-0381, Franklin Circuit Court, Kentucky (Jan. 22, 2019).

¹¹ Although Plaintiffs were permitted to take limited jurisdictional discovery, they were not granted all the discovery they requested, nor have all factual disputes been resolved. In this posture, the *prima facie* standard applies unless the Court holds an evidentiary hearing. See *Schneider v. Hardesty*, 669 F.3d 693, 699 (6th Cir. 2012).

ARGUMENT

I. PLAINTIFFS MAKE A *PRIMA FACIE* SHOWING THAT MALLINCKRODT PLC IS SUBJECT TO JURISDICTION UNDER THE OHIO LONG-ARM STATUTE

Mallinckrodt plc is subject to jurisdiction in Ohio under R.C. § 2307.382(A)(1), which provides for jurisdiction arising from a person's "transacting any business" in Ohio. "[A] person 'transacts business' in Ohio if the business operations set in motion by the defendant have a 'realistic impact' on Ohio commerce." *State ex rel. Atty. Gen. v. Grand Tobacco*, 171 Ohio App. 3d 551, 558 (2007). The defendant need not transact business itself; the activities of its agent in Ohio are sufficient to confer jurisdiction. *See Dayton Superior Corp. v. Yan*, 288 F.R.D. 151, 160 (S.D. Ohio 2012) ("Section (A)(1) provides for personal jurisdiction as to a cause of action arising from the defendant or the defendant's agent transacting any business in Ohio.") Similarly, a defendant may be subject to jurisdiction if it is merely a continuation of a company it acquired that transacted business here.

It is well-established in the Sixth Circuit that a parent company may be subject to personal jurisdiction in a state where its subsidiary is doing business, provided that the corporate separation is fictitious, the parent has held the subsidiary out as its agent, or the parent has exercised undue control over the subsidiary. *Velandra v. Regie Nationale des Usines Renault*, 336 F.2d 292, 296 (6th Cir.1964); *see also Third Nat. Bank in Nashville v. WEDGE Grp. Inc.*, 882 F.2d 1087, 1090 (6th Cir. 1989)(reversing summary judgment based on lack of personal jurisdiction where although defendant never directly conducted business, held title to property, or retained employees in Tennessee, it was the 100% owner of a subsidiary that conducted business in Tennessee; shared officers and directors with subsidiary, and shared tax liabilities with subsidiary).

Moreover, the Sixth Circuit has repeatedly held that the existence of a “middleman” between itself and the forum does not preclude an exercise of personal jurisdiction. *Fortis Corp. Ins. v. Viken Ship Mgmt.*, 450 F.3d 214, 220 (6th Cir. 2006)(reversing a district court’s granting of summary judgment for lack of personal jurisdiction) *citing Tobin v. Astra Pharm. Prods.*, 993 F.2d 528, 544 (6th Cir.1993) (“[The defendant] cannot expect to rely solely on the use of an independent distributor to insulate it from suit.”); *Mott v. Schelling & Co.*, No. 91–1540, 91992 WL 116014, at *6, 1992 U.S. App. LEXIS 13273, at *6 (6th Cir. May 29, 1992)(unpublished) (“ ‘The use of an independent distributor ... in and of itself, will not insulate a non-resident foreign corporation from suit.’ ”) (*quoting Poyner v. Erma Werke GmbH*, 618 F.2d 1186, 1190 (6th Cir.1980)).

A. The Subsidiaries Dominated by Mallinckrodt plc Indisputably Do business in Ohio.

As an initial matter, Mallinckrodt plc’s U.S. subsidiaries Mallinckrodt LLC and SpecGx LLC do not contest personal jurisdiction over them. *See* Mallinckrodt LLC and SpecGx LCC’s Answer to Pl.’s Corrected Second Am. Compl. at 1 n.1 and 165 [ECF No. 1268]; *see also* Manufacturer Defs.’ Joint Mot. to Dismiss Pl.’s Second Am. Compl. at 1 n.1 [ECF No. 499] (objection to personal jurisdiction grounds only to Mallinckrodt plc); *see also* Mem. of Law in Supp. of the Manufacturer Defs.’ Joint Mot. to Dismiss Pl.’s Second Am. Compl. at 1 n.1 [ECF No. 499-1] (again noting only Mallinckrodt plc). Mallinckrodt LLC’s and SpecGx LLC’s Sixtieth Affirmative Defense regarding lack of personal jurisdiction is too raised only as to Mallinckrodt plc. Answer at 165 [ECF No. 1268].

The Mallinckrodt companies sold a lot of opioids into Ohio. According to the Drug Enforcement Agency’s ARCOS data, [REDACTED]

[REDACTED]

[REDACTED] See Chalos Ex. 2 at 2.

[REDACTED]

[REDACTED]

[REDACTED] See also

Chalos Ex. 7, Second Supplemental Expert Report of Craig J. McCann, Ph.D., CFA (Apr. 15, 2019) at Table 1 at 4.

Mallinckrodt indisputably did a lot of business in Ohio. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The conduct of Mallinckrodt plc and its subsidiaries has had a significant harmful impact in Ohio. As Summit County’s Complaint details, Ohio is among the states hardest hit by the opioid epidemic. TAC ¶ 716. Opioid addiction, abuse, and overdose deaths have become the most pressing public health issue facing Ohio. *Id.* Ohio now “leads the country in drug overdose deaths per capita, a rate that continues to rise, overwhelming families, communities, and local governments across the state.” *Id.* The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt. *See* ¶¶ 667-69. Similar pipelines popular with drug couriers developed in other regions of the country: opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky. *Id.*

¹² “Labeler” is defined as “any firm that manufactures or distributes a drug product.” *See* Chalos Ex. 1 at 8.

Even after Ohio's crack-down on pill mills within the state, Mallinckrodt did not prevent suspicious orders from being placed in the state and ultimately diverted to illicit use in Ohio communities. ¶ 713. In November 2010, Mallinckrodt determined that 68% of the purchases by one of its distributors, Cincinnati, Ohio-based KeySource Medical, Inc., were for prescription opioids, and that 91% of this customer's purchasers were sent to Florida. *Id.* During that time, Florida lacked a prescription drug monitoring program similar to Ohio, and traffickers would recruit others to travel to Florida to pick up the drugs Mallinckrodt had shipped there, and bring them back to Ohio, a route that became known as the "Florida Pipeline" or "OxyContin Express."¹³ According to the *Washington Post*, an internal summary of a federal case against Mallinckrodt showed that "Mallinckrodt's response was that—'everyone knew what was going on in Florida but they had no duty to report it.'"¹⁴ In 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids.¹⁵ TAC ¶ 584. The investigation resolved via a settlement agreement signed by representatives of both Mallinckrodt LLC and Mallinckrodt plc (the same person acting in a dual capacity). *See* Fahey Ex. 7.

¹³ Decl. of DEA Diversion Investigator Christopher Kresnak, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9-2 ¶ 3 (S.D. Ohio June 30, 2011).

¹⁴ Lenny Bernstein and Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable: Sixty-Six Percent of All Oxycodone Sold in Florida Came From This Company. But the DEA's Case Against It Faltered*, *Wash. Post*, (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.256b39de1578.

¹⁵ The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders." ¶ 584. Mallinckrodt also admitted that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." ¶ 521. Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." *Id.* Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers." *Id.*

Mallinckrodt marketed its products and disseminated its misrepresentations in the state of Ohio.¹⁶ TAC ¶ 672. Mallinckrodt's marketing and compliance were driven by national policies, plans, and procedures that were the same in Summit County as they were across the country. ¶ 673. This conduct also has been confirmed by the activities observed in Summit County, the impact in its communities, and through discovery in this litigation. *Id.*, *see, e.g.* Chalos Ex. 8, Wickline Dep. Tr. at 75:5-76:11. (same sales messaging for a product nationally, including Ohio); 76:23-25 (the approved promotional materials were the same throughout the country); 90:12-91:13 (incentive compensation plans were the same nationally). Moreover, the president of Mallinckrodt's specialty generics business testified that he knew Mallinckrodt's opioids were being prescribed in Ohio. *See* Chalos Ex. 5, O'Neill Dep. Tr. at 106:21-107:6.

Moreover, the sales representatives from Mallinckrodt who detailed prescribers in Summit County, were among the most frequent visitors. ¶ 674. According to publicly available data, there were at least 149 sales visits, respectively, between the third quarter of 2013 and 2016. *Id.* These visits frequently coincided with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." *Id.*

There is no serious dispute that Mallinckrodt, including through Mallinckrodt LLC and SpecGx LLC, did business in Ohio.

¹⁶ Mallinckrodt is included in the "Marketing Defendants", "RICO Marketing Defendants" and the "RICO Supply Chain Defendants" groups in Summit's Complaint. *See* TAC ¶¶ 100, 28 n.9, 34 n.11, respectively. Mallinckrodt's misrepresentations regarding addiction risk chronicled in Summits Complaint. ¶¶ 223-227, 275, 303, 341-342, 378 - 79; Its work with U.S. Front Groups such as the U.S. Pain Foundation in ¶ 386; membership in trade organizations such as the Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")) in ¶ 535; vast and numerous payments to Speakers' Bureaus (¶ 457 ("Mallinckrodt . . . made thousands of payments to physicians *nationwide*, for activities including participating on speakers' bureaus, providing consulting services, and other services")); payments to physicians nationwide, including in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids (¶ 99).

B. Plaintiffs Make a *Prima Facie* Case that Mallinckrodt plc Is Subject to Jurisdiction Because of Its Unity of Interest and Ownership with Its U.S. Subsidiary

There is no dispute in this case that Mallinckrodt LLC and SpecGx LLC are subject to personal jurisdiction in this case arising from its opioid business here. The issue at bar is whether Mallinckrodt plc is also subject to jurisdiction based on the contacts with Ohio of its subsidiaries. A parent company is subject to jurisdiction based on the activities of its subsidiary “if the parent company exerts so much control over the subsidiary that the two do not exist as separate entities but are one and the same for purposes of jurisdiction.” *Anwar*, 876 F.3d at 848. The Sixth Circuit considers multiple factors to determine if there is sufficient “unity of interest and ownership that goes beyond mere ownership and shared management personnel,” to subject the parent to jurisdiction: “(1) sharing the same employees and corporate officers; (2) engaging in the same business enterprise; (3) having the same address and phone lines; (4) using the same assets; (5) completing the same jobs; (6) not maintaining separate books, tax returns and financial statements; and (7) exerting control over the daily affairs of another corporation.” *Id.* at 849.

Analysis of the evidence pertaining to the relevant factors establishes that Mallinckrodt plc exerts sufficient control over Mallinckrodt LLC and SpecGx LLC to subject it to jurisdiction.¹⁷

(1) Defendants share the same employees and corporate officers

¹⁷ Plaintiffs alleged in the Summit County TAC that Mallinckrodt plc operates in the U.S. and in Ohio through its subsidiaries as a single entity. TAC ¶ 94 (“Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals”). Mallinckrodt plc shares a headquarters with Mallinckrodt LLC in Missouri. *Id.* Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates manufacture, market, sell and distribute pharmaceutical drugs throughout the United States, and in Summit County. *Id.*

Mallinckrodt plc, Mallinckrodt LLC, and SpecGx share common officers and employees. For example, Michael-Bryant Hicks, served as Senior Vice President & General Counsel for both Mallinckrodt LLC and Mallinckrodt plc. Mr. Hicks signed the 2017 DOJ/DEA settlement agreement on behalf of both entities. Fahey Dec. at 13; Fahey Ex. 7 at 14.

Both SpecGx LLC and Mallinckrodt LLC have the common officers between themselves and with Mallinckrodt plc, *see* Fahey Dec. at 16, Fahey Exs. 6 and 28, including:

- Mark Trudeau, President and CEO of Mallinckrodt plc, and Chief Operating Decision Maker (CODM), which makes resource allocation decisions and assesses the performance of the business.
- Matthew K. Harbaugh CFO of Mallinckrodt plc and later Executive Vice President, Chief Financial Officer and President, Specialty Generics (SpecGx LLC).
- Kathleen A. Schaefer, Corporate Controller of Mallinckrodt plc, President of Mallinckrodt LLC, and a member of its Board of Directors.
- Marvin R. Haselhorst, VP-Global Tax pf Mallinckrodt plc, Vice President of Mallinckrodt LLC and a member of its Board of Directors.
- Michael-Bryant Hicks, Senior Vice President & General Counsel of both Mallinckrodt plc and Mallinckrodt LLC
- John Einwalter, Director, Vice President and Treasurer of both Mallinckrodt plc and Mallinckrodt LLC
- Kenneth Goetz, Assistant Secretary of Mallinckrodt LLC and Vice President – Intellectual Property of Mallinckrodt plc.
- Joseph Zaccagnino, Member of Board of Directors of Mallinckrodt plc and of Mallinckrodt LLC.

These common officers of the Mallinckrodt plc and its subsidiaries are not passive: they execute documents on behalf of both the Mallinckrodt plc and its U.S. subsidiaries, Fahey Ex. 7 at 14, Ex. 8 at 15-19; Ex. 11 at 18-20; and Ex. 12 at 112, as well as evaluate the company's operating performance in conjunction with corporate staff, CEO, and the board of directors. Fahey Exs. 6 and 28.

(2) Defendants engage in the same business enterprise;

The foundational governing document establishing Mallinckrodt plc under the Irish Companies Act, “Memorandum and Articles of Association,” states that “the objects for which the Company is established are:”

- “To carry on the business of a healthcare services development company operating in the healthcare field, and to design, manufacture, produce, supply and provide generic and branded pharmaceuticals, active pharmaceutical ingredients and dosage pharmaceuticals...necessary or suitable for the proper treatment of sick or injured persons or patients”.
- “To co-ordinate the administration, finances and activities of any subsidiary companies...to carry on in all its branches the business of a management services company, to act as managers and to direct or co-ordinate the management of other companies or of the business...as may be deemed expedient by the Company’s board of directors...”

Fahey Dec. at 12; Fahey Ex. 2.

Mallinckrodt plc is publicly-traded on the New York Stock Exchange. In its 2017 Annual Report (Form 10-K), filed with the SEC, Mallinckrodt plc notes that it and its subsidiaries “are a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies.” Chalos Ex. 4 at 4. Mallinckrodt plc conducts its “businesses and product sales and marketing strategies” under its trademark name “Mallinckrodt”¹⁸ and/or “the Group,” “us,” “we,” “the Company” or “our,” clearly referring to its subsidiaries. *Id.* at 3. Ninety percent of all sales and 93% of all manufacturing production costs are conducted in the United States.

Fahey Dec. at 12; Fahey Ex. 3.

The 2017 Form 10-K for Mallinckrodt plc further reported to the public and the SEC: “We manufacture controlled substances under DEA quota restrictions and in calendar 2017 we estimated that *we* received approximately 36% of the total DEA quota provided to the U.S.

¹⁸ Parent uses its trademark name “Mallinckrodt™” and its website www.mallinckrodt.com on its Medication Guide that has been approved by the U.S. Food and Drug Administration. The Medication Guide identifies its U.S. subsidiary Mallinckrodt, Inc. or SpecGx LLC, as the “distributor” or “manufactured for”.

market for the controlled substances *we* manufacture.” Chalos Ex. 4 at 8 (emphasis added). The 10-K also reports “significant products and product families in our Specialty Generics product portfolio,” including hydrocodone and hydrocodone-containing tablets and oxycodone and oxycodone-containing tablets. *Id.* Mallinckrodt plc also calls itself “an industry leader in the effort to address prescription drug diversion and misuse in the United States.” Chalos Ex. 9.

(3) Defendants use the same assets;

Mallinckrodt plc’s Annual Report further notes that, in addition to its principal executive offices in the U.K., “we have other locations in the United States (‘U.S.’), most notably *our corporate shared services office* in Hazelwood, Missouri, *our Specialty Brands commercial headquarters* in Bedminster, New Jersey and *our Specialty Generics headquarters and technical development center* in Webster Groves, Missouri.” Chalos Ex. 4 at 5 (emphasis added). The “Shared facilities,” “corporate shared services office” and “corporate assets used to manage the Company’s total business” in the U.S. include “IT, Finance, Human Resources, Corporate Compliance, Communications & Government Affairs.” Fahey Dec. at 13; Fahey Ex. 23 at 73. Mallinckrodt plc also reported at that time that “[a]t December 29, 2017, we had approximately 3,900 employees, approximately 3,400 of which are based in the U.S.” Chalos Ex. 4 at 20.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Fahey Dec. at 16; Fahey Ex. 21; *see also* Fahey Dec. at 7-8 (Charts showing Mallinckrodt plc's use of revenue from its U.S. opioids businesses).

[REDACTED]

[REDACTED]

[REDACTED] SpecGx's business is manufacturing and distributing generic opioids in the United States, including Ohio. TAC ¶ 94.

(4) Defendants did not maintain separate books and financial statements;

Mallinckrodt plc, files its consolidated financial results with the SEC and Irish Statutory Accounts. Fahey Dec. at 12; Fahey Exs. 1 and 16. It offsets its losses against its gains as one "Group,"¹⁹ which includes Mallinckrodt LLC and SpecGx LLC. *Id.* Mallinckrodt plc, through its board of directors and staff at corporate headquarters, maintains "Group Accounting Policies" Fahey Dec. at 16; Fahey Ex. 22.

Mallinckrodt plc is also required by its lenders to "limit" the disposition of all subsidiaries' cash flows, capital expenditures spending and requires submission of annual budgets on a "consolidated basis" approved by a Financial Officer of Mallinckrodt plc. Fahey

¹⁹ The term "Group" was mentioned in 523 instances in the 2017 Irish Statutory Accounts. *See* Fahey Dec. at 12 n.6, Fahey Exs. 1 and 16.

Dec. at 14; Fahey Ex. 11 at 2, 55, 62, 63, 65 & 179. Mallinckrodt plc “borrows” money on “its receivable securitization” on accounts receivable generated from sales of opioid medications through Mallinckrodt LLC which was required to maintain “Lock-Box Accounts” “of all collections of its receivables for the benefits of the Secured Parties” with “priority” restrictions on the “distribution” of the receivables “collections”. Fahey Dec. at 14; Fahey Ex. 12 at 3-4, 46. Moreover, the Term Loan and Revolving Credit Facility “are fully and unconditionally guaranteed by Mallinckrodt plc, certain of its direct or indirect wholly-owned U.S. subsidiaries and each of its direct or indirect wholly-owned subsidiaries that owns directly or indirectly any wholly-owned U.S. subsidiaries and certain of its other subsidiaries (collectively, ‘the Guarantors’).” Fahey Dec. at 14; Fahey Ex. 12 at 2-3. In addition, Mallinckrodt plc calculates and reports its Net Debt Leverage Ratio based on its consolidated financial statements, which includes revenue from Mallinckrodt LLC and SpecGx LLC. Fahey Dec. at 14; Fahey Ex. 13.

Mallinckrodt plc, as a result of owning and operating its U.S. subsidiaries (“the Group”), enjoyed substantial tax savings and tax benefits in the United States, including: \$456.9 million in tax benefits in 2017 from the U.S. Tax Cuts & Jobs Act (“TCJA”); and Millions of dollars in tax benefits from the U.S. Orphan Drug & Research Tax Credits. Fahey Dec. at 8, 18; Fahey Ex. 29.

(5) Mallinckrodt plc exerts control over the daily affairs of Mallinckrodt LLC and SpecGx.

Mallinckrodt plc has reported that 90% of its sales and 93% of its manufacturing production costs are conducted in the United States. Fahey Dec. at 12; Fahey Ex. 3. In 2013, in its Master Q&A for investors and media, Mallinckrodt plc state: “We have a strong foundation - 146 years of experience - in managing controlled substances. *We* are the largest U.S. supplier of

opioid pain medications and other highly controlled substances” Fahey Exs. 9 at 6 (emphasis added).

Mallinckrodt plc controls its subsidiaries’ “marketing and sales strategies” and “promotional efforts” and “developed a robust Compliance Program” and “have implemented an internal cross-functional processes to review and approve product-specific materials, presentations and external communications to address the risk of misbranding or mislabeling our products through our promotional efforts”. Fahey Dec. at 6, 15; Fahey Ex. 16 at 9. As it stated in Mallinckrodt plc’s 2017 10-K, “[o]ur ability to maintain and increase net sales. . . depends on several factors, including our ability to increase market demand for products through our own marketing and support of our sales force.” Fahey Dec. at 15; Fahey Ex. 16 at 9 (emphasis added). Moreover, when pressed by a shareholder to report on measures Mallinckrodt plc has taken to “manage financial and reputational risks related to the opioid crisis in the U.S.,” Mallinckrodt plc responded, “making and selling pharmaceutical products, such as opioids, and making the complex judgments associated with managing risks associated with operating its businesses, including ensuring compliance with laws and regulations, are the ordinary business of management, overseen by the Board and its committees.” See Chalos Ex. 10 at 40 (emphasis added).

An example of the domination exerted by Mallinckrodt plc, in 2014, it was Mallinckrodt plc itself, and not any U.S. subsidiary, that announced FDA approval of Xartemis XR, a drug containing oxycodone and acetaminophen. Chalos Ex. 11. The “Contacts” listed in the Xartemis press release are labeled as “Mallinckrodt plc,” but the phone numbers provided include the Missouri 314 area code. *Id.* One of those “Contacts,” Mallinckrodt’s manager of communications, Lynn Phillips, who worked for the company in the United States and has a law

degree, [REDACTED] Chalos Ex. 12
at 17:13-19.

Mallinckrodt plc also exerts its domination by controlling all of its managements' and employees' "Stock and Incentive Plan/Option Award" and "Supplemental Savings & Retirement Plan". Fahey Dec. at 15; Fahey Ex. 15.

Mallinckrodt plc reports its net sales by business segment (not by subsidiary) *i.e.*, generics and branded opioid and non-opioid (branded) medications. Fahey Dec at 7. Reporting consolidated financial results by operating segment as required by the SEC under one "Group" of "Trading Partners" allows Mallinckrodt plc to offset its losses against its gains as a single economic entity. *Id.* Segment reporting allows the CEO and common officers of the Parent and its U.S. subsidiaries to exercise additional control over the single economic entity through control of how the business segments are constructed, what business metrics are reported and the allocation of the single economic entity resources. *Id.*

This notion of a unified Mallinckrodt group irrespective of corporate formalities is consistent with the testimony of Jeff Kilper, Senior Director Finance, Specialty Generics, that he pays no attention to legal entities, but focuses on the particular businesses of Mallinckrodt. Chalos Ex. 13, Kilper Dep. Tr. at 46:10-21; *see also* 8:13-23, 9:2-9, 12:19-23, 13:11-14. Plaintiffs note that although Mr. Kilper [REDACTED] [REDACTED] signed a Sarbanes-Oxley compliance form for Mallinckrodt plc in 2015, listing his own then-title as "Director, Finance - Hospital Therapies of *Mallinckrodt plc*" (emphasis added), he has always worked in St. Louis. *Id.* at 8; Chalos Ex. 14, Sarbanes-Oxley compliance form; Chalos Ex.15, Kilper LinkedIN profile.

It is also consistent with the testimony of Hugh O'Neill, executive vice president and chief commercial officer, who despite being in the senior leadership didn't know whether Mallinckrodt plc or some other entity pays his salary [REDACTED]

[REDACTED]

[REDACTED] Chalos Ex. 5, O'Neill Dep. Tr. at 12:17-23. Mr. O'Neill also did not know which entity the board of directors were nominally associated with: [REDACTED]

[REDACTED]

[REDACTED] *Id.* at 17:22-18:7.

Finally, Mallinckrodt plc has acted, and is acting, to dispose of the U.S. opioids business without regard the corporate formalities of the U.S. entity. In its December 30, 2016 quarterly report, Mallinckrodt plc reported that the "goodwill" of its opioid business segment was impaired; Mallinckrodt plc began attempts to sell the business. Chalos Ex. 16 at 39, 2016 MNK 10-Q. Thereafter, on February 22, 2018, Mallinckrodt plc, acting through its Board of Directors, to "further execute upon our strategic vision" authorized the disposition of its opioids business, and hired Credit Suisse Securities, LLC as the exclusive financial adviser to pursue the sale. Mallinckrodt plc then caused the transfer of its opioid business operations and assets from Mallinckrodt, LLC to SpecGx, LLC. Chalos Ex. 4 at 4. Nine months later on December 6, 2018, MNK, plc announced a new plan to spin off the opioids business into a new publicly held entity that "will assume the Mallinckrodt name" through SpecGx, LLC. Chalos Ex. 17. In other words, Mallinckrodt plc authorized the sale of opioids business in theory belonging to Mallinckrodt LLC and SpecGX LLC, to separate its impaired opioids business from its unimpaired new branded products business.

All of these activities, and others, clearly establish a *prima facie* case that Mallinckrodt plc exerts so much control over the subsidiaries that the companies “do not exist as separate entities but are one and the same for purposes of jurisdiction.” *Anwar*, 876 F.3d at 848

C. Plaintiffs Have Established a *Prima Facie* Case that Mallinckrodt plc Is Subject to Jurisdiction as the Successor to Covidien

Jurisdiction as a successor may attach if the successor corporation expressly or impliedly agreed to assume the relevant liability; if the transaction amounts to a *de facto* consolidation or merger; or if the buyer corporation is merely a continuation of the seller corporation. *See Opportunity Fund, LLC v. Epitome Sys., Inc.*, 912 F. Supp. 2d 531, 541 (S.D. Ohio 2012), *citing Welco Indus., Inc. v. Applied Cos.*, 67 Ohio St.3d 344 (1993).

Here, Mallinckrodt plc agreed to and is required to indemnify and/or accept obligations of third-party claims on “matters related to our business”, such as Covidien on “assumed or retained liabilities arising out of its Separation Agreement.” and other third parties such as “purchasers” of businesses it sold, environmental liabilities and the DEA. Fahey Dec. at 7, 15; Fahey Exs. 7 and 17.

Although Mallinckrodt plc makes no mention of [REDACTED]

[REDACTED] in its Motion to Dismiss, it is clear that, [REDACTED]
[REDACTED]
[REDACTED]

D. Plaintiff Makes a *Prima Facie* Case that Mallinckrodt plc Is Subject to Jurisdiction Because of Its Complicity in the Acts of Others

Mallinckrodt plc may also be subject to jurisdiction under § 2307.382(A)(7), which provides that a court may exercise jurisdiction “over a person who acts directly or by an agent, as to a cause of action arising from the person’s. . . [c]ausing tortious injury to any person by a criminal act, any element of which takes place in this state, which he commits or in the

commission of which he is guilty of complicity.” The claims against Mallinckrodt plc include claims under the Racketeer-Influenced and Corrupt Organizations Act (“RICO”) which, by definition, involve criminal predicate acts. *See* TAC ¶¶ 815-78. Under § 2307.382(A)(7), Mallinckrodt plc need *not* have, itself, committed any of those predicate acts (only a single element of which needs to have occurred in Ohio), so long as it is guilty of complicity in them. Thus, to the extent that Mallinckrodt plc was complicit in the criminal conduct of Mallinckrodt LLC and/or SpecGx LLC that gives rise to Plaintiff’s RICO claims, it is subject to jurisdiction under R.C. § 2307.382.

II. THE JURISDICTIONAL ISSUES ARE INTERTWINED WITH THE MERITS

Additionally, here, given that Plaintiffs have established a *prima facie* basis for personal jurisdiction, the Court should reserve any substantive factual determinations for trial. As the Sixth Circuit observed, “where the disputed jurisdictional facts are intimately intertwined with the parties’ dispute on the merits, a trial court should not require plaintiffs to mount “proof which would, in effect, establish the validity of their claims and their right to the relief sought.” *Serras*, 875 F.2d at 1215. Moreover, as the Sixth Circuit further observed, “[i]n many cases, then, a district court may find sound reasons to rule, on the basis of written submissions, that the plaintiff has made her *prima facie* showing that the court has personal jurisdiction over a defendant, and to reserve all factual determinations on the issue for trial.” *Id.*

Here, much of the same proof that would establish Mallinckrodt plc’s substantive liability, such as its direct or indirect activities falsely marketing opioids, failing to monitor suspicious orders, and participating in a RICO enterprise, would also establish personal jurisdiction over Mallinckrodt plc. The proof at trial will largely overlap among the entities and the entities are represented by the same counsel, thereby minimizing the risk of the parties and

court unnecessarily expended resources at trial even if the fact finder later concludes that personal jurisdiction is lacking over Mallinckrodt plc.

In short, Plaintiffs have plausibly alleged that Mallinckrodt plc engaged in the alleged misconduct, established a *prima facie* case against it, and has come forth with sufficient factual evidence to warrant an exercise of personal jurisdiction over Mallinckrodt plc. Even hampered by severely limited jurisdictional discovery, Plaintiffs have more than met their burden at this stage of the litigation. Accordingly, to the extent there are remaining factual disputes, the Court should leave for trial the final determination of the overlapping substantive relevant facts that would establish both substantive liability and personal jurisdiction. *Id.*

III. JURISDICTION OVER MALLINCKRODT PLC COMPORTS WITH DUE PROCESS

Assertion of jurisdiction over Mallinckrodt plc also comports with due process. In *AlixPartners, LLP v. Brewington*, the Sixth Circuit set forth a three-part test:

First, the defendant must purposefully avail himself of the privilege of acting in the forum state or causing a consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of defendant or consequences caused by the defendant must have a substantial enough connection with the forum state to make the exercise of jurisdiction over the defendant reasonable.

AlixPartners v. Brewington, 836 F.3d 543, 549–50 (6th Cir. 2016).

The test is easily satisfied here. As discussed above, Mallinckrodt plc sold its opioid products throughout the United States, including within the State of Ohio. Although Mallinckrodt plc claims that the company that sold those drugs was Mallinckrodt LLC and/or SpecGx LLC, not Mallinckrodt plc, the evidence discussed above establishes that *either* Mallinckrodt plc sold the drugs directly *or* that it so disregarded the purported separateness of Mallinckrodt LLC and/or SpecGx LLC that the sales here can be attributed to it, *or* that it is the successor to one or more companies that sold generic opioids here *or* that it conspired with

Mallinckrodt LLC and/or SpecGx LLC to commit criminal acts here. In any of these scenarios, there can be no doubt that the assertion of jurisdiction over Mallinckrodt plc comports with due process.

The sale of opioids in Ohio constitutes purposeful availment of the privilege of acting in the forum. Plaintiffs' claims arise, in part, from the sale of those opioids here. And Mallinckrodt plc's acts – selling opioids in Ohio – are sufficiently connected to the opioid crisis in Ohio to make the exercise of jurisdiction reasonable. [REDACTED]

[REDACTED]. *See Estate of Thomson ex rel. Estate of Rakestraw v. Toyota Motor Corp. Worldwide*, 545 F.3d 357, 362 (6th Cir. 2008) (assertion of personal jurisdiction over the successor of a corporation that would be subject to jurisdiction comports with due process). Finally, the assertion of jurisdiction based on the acts of a co-conspirator also comports with jurisdiction, where, as here, the focus of the conspiracy was to evade U.S. laws and regulations pertaining to the distribution of opioids in the United States, including in Ohio, and Plaintiff has produced evidence of Mallinckrodt plc's complicity, thus providing the requisite contacts and nexus. *See Newsome v. Gallacher*, 722 F.3d 1257, 1265 (10th Cir. 2013) (where one co-conspirator acts within the forum and conspiracy directed at the forum, minimum contacts sufficient to exercise jurisdiction over another co-conspirator); *Melea, Ltd. v. Jawer SA*, 511 F.3d 1060, 1069-70 (10th Cir. 2007) (acts of a co-conspirator within the forum may, in some cases, subject another co-conspirator to the forum's jurisdiction, where plaintiff alleges facts that would support a *prima facie* showing of conspiracy and where conspiracy was directed at the forum).

No Mallinckrodt defendant has disputed that Mallinckrodt LLC and SpecGx LLC are subject to jurisdiction in Ohio and that such jurisdiction comports with due process.

Mallinckrodt plc's motion turns entirely on its contention that it is distinct from Mallinckrodt LLC and/or SpecGx LLC. The acts carried out by Mallinckrodt LLC and SpecGx LLC – the marketing and sale of opioids into Ohio– are properly attributable to Mallinckrodt plc. It then follows that jurisdiction over Mallinckrodt plc is reasonable as well. Similarly, Mallinckrodt plc does not dispute that its predecessor Covidien sold opioids in Ohio. Mallinckrodt plc is the successor to Covidien and, on that separate basis, jurisdiction is proper. Finally, Mallinckrodt plc was complicit in criminal activity of Mallinckrodt LLC, SpecGx LLC, and other defendants, again rendering jurisdiction proper. Plaintiffs have more than established a *prima facie* case that these contentions are well supported by the facts.

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Mallinckrodt plc's Motion to Dismiss for Lack of Personal Jurisdiction.

Respectfully Submitted:

DATED: June 21, 2019

/s/ Elizabeth J. Cabraser

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CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2019, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF Systems.

DATED: June 21, 2019

/s/ Elizabeth J. Cabraser
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